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10/025,964 12/19/2001 Leonard Schlessinger KAIS-002 2186 20872 7590 11/02/2005 EXAMINER MORRISON & FOERSTER LLP 425 MARKET STREET ART UNIT PAPER NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Please find below and/or attached an Office communication concerning this application or proceeding.

	· · · · · · · · · · · · · · · · · · ·	Application No.	Applicant(s)			
Office Action Summary		10/025,964	SCHLESSINGER ET AL.			
		Examiner	Art Unit			
		Herng-der Day	2128			
Period fo	The MAILING DATE of this communication app or Reply	ears on the cover sheet with the c	orrespondence address			
WHIC - Exter after - If NO - Failu Any r	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DATE in a solution of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. In period for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI	L. lely filed the mailing date of this communication.			
Status						
1) 又	Responsive to communication(s) filed on 24 Ju	ne 2005.				
	This action is FINAL . 2b) ☐ This action is non-final.					
	Since this application is in condition for allowar		secution as to the merits is			
	closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	3 O.G. 213.			
Dispositi	on of Claims					
4)🖂	Claim(s) 98-150 is/are pending in the application	on.				
	4a) Of the above claim(s) is/are withdraw	vn from consideration.				
5)	Claim(s) is/are allowed.					
6)⊠	Claim(s) 98-150 is/are rejected.					
7)	7) Claim(s) is/are objected to.					
8)[Claim(s) are subject to restriction and/or	election requirement.				
Applicati	on Papers					
9)[The specification is objected to by the Examine	·.				
10)⊠ The drawing(s) filed on <u>24 June 2005</u> is/are: a) accepted or b)⊠ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
	Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) 🔲 -	The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.			
Priority u	nder 35 U.S.C. § 119					
	Acknowledgment is made of a claim for foreign ☐ All b) ☐ Some * c) ☐ None of:	priority under 35 U.S.C. § 119(a)	-(d) or (f).			
	1. Certified copies of the priority documents	have been received.				
	Certified copies of the priority documents	have been received in Application	on No			
	3. Copies of the certified copies of the priori	ty documents have been receive	d in this National Stage			
	application from the International Bureau	` ''				
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment						
	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summary (Paper No(s)/Mail Dat				
3) 🔲 Inform	nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) No(s)/Mail Date	5) Notice of Informal Pa				

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DETAILED ACTION

1. This communication is in response to Applicants' Reply ("Reply") to Office Action dated

February 25, 2005, mailed June 24, 2005.

1-1. Claims 1-97 have been canceled. Claims 98-150 have been added. Claims 98-150 are

pending.

1-2. Claims 98-150 have been examined and rejected.

Drawings

2. The proposed drawing corrections to Figure 2 received June 24, 2005, has been approved. However, the replacement sheet of Figure 2 is not legible. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the Examiner, the Applicants will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The objections to the specification have been withdrawn.

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Claim Objections

4. Claims 119 and 136 are objected to because of the following informalities. Appropriate correction is required.

- 4-1. Regarding claim 119, an end sentence period is missing.
- **4-2.** Regarding claim 136, an end sentence period is missing.

Claim Rejections - 35 USC § 112

- 5. The following is a quotation of the first paragraph of 35 U.S.C. 112:
 - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 6. Claims 98-150 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.
- 6-1. All the independent claims recite the limitation, "determining, from the values for the one or more mathematical parameters, one or more distribution-function parameters for specifying one or more distribution functions for the one or more mathematical parameters". Applicants provide an "Example 1" to illustrate the workings of the present invention. As described in paragraph [00048], there are 123 individuals or values of k in the sample of Example 1 and the samples of the distribution for each of the seven f_j are shown histogrammatically in each of FIGS. 3-9A. However, the total "Number in Bin" in each of FIGS. 3-9A is greater than 123.

Therefore, without undue experimentation, it is unclear for one skilled in the art how to derive a corresponding distribution function based on the teachings of the "Example 1" as disclosed in paragraph [00048] and shown in each of FIGS. 3-9A before one or more distribution-function parameters can be determined.

- 6-2. Claims 111-113, 129-131, and 146-148 recite the limitation "hybrid functions". However, as described in paragraph [00042], "the Hybrid expansion is not guaranteed to converge". Therefore, without undue experimentation, it is unclear for one skilled in the art how to make and/or use the invention by including hybrid functions as basis functions because the convergence of Hybrid expansion is not guaranteed.
- **6-3.** Claims not specifically rejected above are rejected as being dependent on a rejected claim.
- 7. Claims 7, 120, and 137 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
- 7-1. Claims 7, 120, and 137 recite the limitation "separating the initial values into bins with corresponding bin values; and determining the values for the one or more mathematical parameters by replacing the initial values with the bin values". As described in paragraph [00048], only bin range has been disclosed. "Bin values" do not appear to have support in the original disclosure unless bin values equate bin ranges.

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Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

- 9. Claims 98-150 are rejected under 35 U.S.C. 101 because the inventions as disclosed in claims are directed to non-statutory subject matter.
- 9-1. Regarding claims 98-150, it appears to be directed merely to the manipulation of an abstract idea for generating a continuous mathematical model without resulting in a practical application producing a concrete, useful, and tangible result.
- 9-2. Regarding claims 117-133, the apparatus comprising only executable instructions for generating a continuous mathematical model. Therefore, it is software programming per se. In other words, the claimed invention taken as a whole is directed to a mere program listing and hence nonstatutory. See MPEP §2106 (IV) (B).
- 9-3. The Examiner acknowledges that even though the claims are presently considered non-statutory they are additionally rejected below over the prior art. The Examiner assumes the Applicants will amend the claims to overcome the 101 rejections and thus make the claims statutory.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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11. Claims 98-100, 105, 107-111, 114, 116-118, 123, 125-129, 133-135, 140, 142-146, and 150, are rejected under 35 U.S.C. 102(b) as being anticipated by Newman, "Model Reduction via the Karhunen-Loeve Expansion Part I: An Exposition", Institute for Systems Research and Electrical Engineering Department, University of Maryland, April 1996, pages 1-19, (IDS A, June 27, 2003).

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11-1. Regarding claim 98, Newman discloses a computer-implemented method for generating a continuous mathematical model of a feature common to subjects in a subject group, the method comprising:

determining a plurality of sample data sets corresponding to the subjects in the subject group (obtain empirical data, page 17, paragraph 1);

determining, from the sample data sets, a plurality of values for one or more mathematical parameters $(a_n(t), page 17, line 6)$ corresponding to one or more basis functions $(\phi_n(x), page 17, line 6)$ for the continuous mathematical model (v(t,x), page 17, line 6); and

determining, from the values for the one or more mathematical parameters, one or more distribution-function parameters for specifying one or more distribution functions for the one or more mathematical parameters (the Fourier coefficients $a_n(t)$ are time-dependent random variables, page 8, paragraph 3; for only one mathematical parameter, $a_1(t)$ specifying one distribution function), wherein a summation of the one or more basis functions multiplied by sampled values of the one or more distribution functions provides the continuous mathematical model of the feature (equation of v(t,x), page 17, line 6).

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11-2. Regarding claim 99, Newman further discloses determining the sample data sets includes receiving the sample data sets from an external data source and storing the sample data sets in a computer memory (obtain empirical data via experiment, page 17, paragraph 1).

- 11-3. Regarding claim 100, Newman further discloses determining the sample data sets includes measuring values for the feature and storing the values for the feature in the external data source (obtain empirical data via experiment, page 17, paragraph 1).
- 11-4. Regarding claim 105, Newman further discloses comprising:

simulating the feature by generating sampled values of the distribution functions by computer (equation of v(t,x), page 17, line 6); and

displaying at least one statistical property of the simulated feature ({vt,x} is a stochastic process with zero mean, page 3, line 18).

- 11-5. Regarding claim 107, Newman further discloses the feature is a first feature selected from a plurality of features; and values for the features other than the first feature and values for the one or more distribution-function parameters specify the one or more distribution functions for the one or more mathematical parameters (the quantity of interest could be mass, energy, or momentum, page 2, paragraph 5).
- 11-6. Regarding claim 108, Newman further discloses comprising:

simulating the first feature by computer, for given values of the features other than the first feature, by generating sampled values of the one or more distribution functions (equation of v(t,x), page 17, line 6); and

displaying at least one statistical property of the simulated first feature ({vt,x} is a stochastic process with zero mean, page 3, line 18).

- 11-7. Regarding claim 109, Newman further discloses the one or more basis functions include a single basis function and the summation includes a single term (N=1 in equation of v(t,x), page 17, line 6).
- 11-8. Regarding claim 110, Newman further discloses the one or more basis functions include a plurality of orthogonal functions over a continuous interval (an orthonormal basis $\{\phi_1, \phi_2, ...\}$, page 8, paragraph 3).
- 11-9. Regarding claim 111, Newman further discloses the one or more basis functions include one or more hybrid functions that characterize features common to the subject group over a continuous interval (equation of v(t,x), page 18, line 8).
- 11-10. Regarding claim 114, Newman further discloses a computer determines the values for the one or more mathematical parameters and the one or more distribution-function parameters (solving the differential equations to get a, page 18, lines 3-4).
- 11-11. Regarding claim 116, Newman further discloses the one or more distribution functions include at least one normal distribution function and the one or more distribution-function parameters include at least one corresponding standard-deviation parameter (introduce a probabilistic structure on the ensemble, page 3, lines 1-3).
- 11-12. Regarding claims 117-118, 123, 125-129, and 133, these apparatus claims include equivalent method limitations as in claims 98-99, 105, 107-111, and 116 and are anticipated using the same analysis of claims 98-99, 105, 107-111, and 116.
- 11-13. Regarding claims 134-135, 140, 142-146, and 150, these medium claims include equivalent method limitations as in claims 98-99, 105, 107-111, and 116 and are anticipated using the same analysis of claims 98-99, 105, 107-111, and 116.

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Claim Rejections - 35 USC § 103

- 12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 13. Claims 101, 112, 115, 119, 130, 132, 136, 147, and 149 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newman, "Model Reduction via the Karhunen-Loeve Expansion Part I: An Exposition", Institute for Systems Research and Electrical Engineering Department, University of Maryland, April 1996, pages 1-19, (IDS A, June 27, 2003), in view of Brown, U.S. Patent 5,956,501 issued September 21, 1999, (IDS C, December 19, 2001).
- 13-1. Regarding claims 101, 112, and 115, Newman fails to expressly disclose (1) the sample data sets include values of blood pressure for the subjects in the subject group; (2) the one or more hybrid functions include a first function for blood pressure and a second function for cholesterol level; and (3) the subjects are biological subjects and the feature is a biological feature. Nevertheless, Newman discloses model reduction via the K-L expansion for flows.

Brown discloses a disease simulation system for predicting the effect of patient self-care actions on the disease control parameter. Examples of these disease control parameters include blood pressure, cholesterol, etc. (column 1, lines 15-20). Because Brown's disease simulation system is sufficiently general and accurate it may be used to simulate many different types of diseases and may also be easily customized to an individual patient (column 2, lines 17-25).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Newman to incorporate the teachings of Brown to obtain the invention as specified in claims 101, 112, and 115, because Brown's disease simulation system would benefit from Newman's model reduction via the K-L expansion at least for blood flow.

- **13-2.** Regarding claims 119, 130, and 132, these apparatus claims include equivalent method limitations as in claims 101, 112, and 115, and are unpatentable using the same analysis of claims 101, 112, and 115.
- 13-3. Regarding claims 136, 147, and 149, these medium claims include equivalent method limitations as in claims 101, 112, and 115, and are unpatentable using the same analysis of claims 101, 112, and 115.
- 14. Claims 102-104, 106, 120-122, 124, 137-139, and 141 are rejected under 35 U.S.C. 102(b) as being unpatentable over Newman, "Model Reduction via the Karhunen-Loeve Expansion Part I: An Exposition", Institute for Systems Research and Electrical Engineering Department, University of Maryland, April 1996, pages 1-19, (IDS A, June 27, 2003), in view of Applicants' assertions.
- 14-1. Regarding claim 102, Newman discloses a computer-implemented method for generating a continuous mathematical model of a feature common to subjects in a subject group in claim 98 including determining the Fourier coefficients. Newman fails to expressly disclose: determining initial values for the one or more mathematical parameters according to an optimization criterion; separating the initial values into bins with corresponding bin values; and determining

the values for the one or more mathematical parameters by replacing the initial values with the bin values.

Applicants assert, as described in paragraph [00028], "There are many ways well known to those skilled in the art to estimate the specific values for the mathematical parameters, depending on how the expansion functions are chosen".

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Newman to incorporate the Applicants' assertions to obtain the invention as specified in claim 102 because the detail steps are well known need no further teachings.

14-2. Regarding claim 103, Newman discloses a computer-implemented method for generating a continuous mathematical model of a feature common to subjects in a subject group in claim 98 including determining the Fourier coefficients. Newman fails to expressly disclose determining the one or more mathematical parameters includes calculating the values for the one or more mathematical parameters from the sample data sets according to an optimization criterion.

Applicants assert, as described in paragraph [00040], "The underlying theory for this type of expansion are well known functional analysis techniques. One advantage of using this method is that the power of the theory of functional analysis can be applied to the estimation procedure. Moreover, many properties of the K-L decomposition require the use of this type of expansion".

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Newman to incorporate the Applicants' assertions to obtain

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the invention as specified in claim 103 because the detail steps are well known and need no further teachings.

14-3. Regarding claim 104, Newman discloses a computer-implemented method for generating a continuous mathematical model of a feature common to subjects in a subject group in claim 98 including determining the Fourier coefficients. Newman fails to expressly disclose determining the one or more distribution-function parameters includes calculating the one or more distribution-function parameters from the values for the one or more mathematical parameters according to an optimization criterion.

Applicants assert, as described in paragraph [00072], "Determining distribution of data samples from a set of samples is a standard problem which is often addressed using maximum likelihood techniques".

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Newman to incorporate the Applicants' assertions to obtain the invention as specified in claim 104 because the detail steps are well known and need no further teachings.

14-4. Regarding claim 106, Newman discloses a computer-implemented method for generating a continuous mathematical model of a feature common to subjects in a subject group in claim 98 including determining the Fourier coefficients and orthonormal basis functions. Newman fails to expressly disclose: selecting a plurality of initial basis functions; determining a plurality of values for a plurality of mathematical parameters corresponding to the initial basis functions; determining, from the values for the mathematical parameters corresponding to the initial basis

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functions, a correlation matrix for the initial basis functions; and determining, from the correlation matrix, the one or more basis functions according to a de-correlation criterion.

Applicants assert, as described in paragraph [00056], "This approach is closely related to both the principal component method (PCM) and the method of factor analysis and is a central feature of the K-L decomposition".

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Newman to incorporate the Applicants' assertions to obtain the invention as specified in claim 106 because the detail steps are well known and need no further teachings.

- 14-5. Regarding claims 120-122 and 124, these apparatus claims include equivalent method limitations as in claims 102-104 and 106, and are unpatentable using the same analysis of claims 102-104 and 106.
- **14-6.** Regarding claims 137-139 and 141, these medium claims include equivalent method limitations as in claims 102-104 and 106, and are unpatentable using the same analysis of claims 102-104 and 106.

Applicants' Arguments

- 15. Applicants argue the following:
- 15-1. Claim Rejections Under 35 USC § 112
- (1) "The Examiner has not shown how the exact total number of bin items is substantially different from the indicated number in a way that would require 'undue experimentation'" (page 19, last paragraph through page 20, first paragraph, Reply).

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(2) All the claims rejected under 35 U.S.C § 112, second paragraph, have been cancelled (page 20, paragraph 4, Reply).

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- 15-2. Claim Rejections Under 35 USC § 101
- (3) Claims 1-97 rejected under 35 USC § 101 have been cancelled (page 20, paragraph 6, Reply).
- 15-3. Claim Rejections Under 35 USC § 102 and 35 USC § 103
- (4) All the claims rejected under 35 USC § 102 and 35 USC § 103 have been cancelled (page 20, last paragraph through page 21, first paragraph, Reply).
- (5) "there is no disclosed connection between the 'empirical data flow' (page 14) and the 'time-dependent random variables' (page 8) with applicability to 'one or more distribution functions for the one or more mathematical parameters' as claimed in claim 98" (page 21, paragraph 4, Reply).
- (6) "Newman does disclose an application to Galerkin's method (page 16, section 3.6) as applied to PDEs (partial differential equations) with a 'separation of variables solution' in terms of the eigenfunctions (page 16, bottom of page); however, this solution approach leads to differential equations (not 'distribution functions') for the coefficients $a_i(t)$ (page 17, bottom of page)" (page 21, last paragraph through page 22, first paragraph, Reply).
- (7) "With respect to claim 111, Brown does not disclose 'one or more hybrid functions that characterize features common to the subject group over a continuous interval" (page 22, paragraph 2, Reply).

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Response to Arguments

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- 16. Applicants' arguments have been fully considered.
- 16-1. Applicants' argument (1) is not persuasive. Applicants are silent why, based on the teachings of the "Example 1", one skilled in the art with 123 samples would derive a corresponding distribution function with total number in all bins more than 123 samples. If the figures do not support Applicants' teaching, Applicants should file a Continuation in Part to correct the deficiency.
- **16-2.** Applicants' argument (2) is persuasive. The rejections of claims 11, 12, 18-31, 37, 38, 40, 42, 43, 46, 49-64, 70, 71, 73, 75, 76, 79, 80, and 82-97 under 35 U.S.C. 112, second paragraph, in Office Action dated February 25, 2005, have been withdrawn.
- 16-3. Applicants' argument (3) is persuasive. The rejections of claims 1-97 under 35 U.S.C. 101, in Office Action dated February 25, 2005, have been withdrawn.
- 16-4. Applicants' argument (4) is persuasive. The rejections of claims 1-97 under 35 U.S.C. 102(b)/103(a) in Office Action dated May 19, 2004, have been withdrawn.
- 16-5. Applicants' argument (5) is not persuasive. Newman discloses the Fourier coefficients $a_n(t)$ are time-dependent random variables at page 8, paragraph 3. Therefore, at least for only one mathematical parameter, $a_1(t)$ specifies one distribution function which meets the claimed limitation.
- 16-6. Applicants' argument (6) is not persuasive. Newman discloses the Fourier coefficients $a_n(t)$ are time-dependent random variables at page 8, paragraph 3. Therefore, at least for only one mathematical parameter, $a_1(t)$ specifies one distribution function which meets the claimed limitation. Furthermore, Newman discloses an application to Galerkin's method. The solution

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approach not only leads to differential equation (not 'distribution functions') for the coefficient $a_1(t)$ but also the coefficient $a_1(t)$ itself by solving the differential equation.

16-7. Applicants' argument (7) is most in view of the new ground(s) of rejection.

Conclusion

17. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

18. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Herng-der Day whose telephone number is (571) 272-3777. The Examiner can normally be reached on 9:00 - 17:30.

Any inquiry of a general nature or relating to the status of this application should be directed to the TC 2100 Group receptionist: (571) 272-2100.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Kamini S. Shah can be reached on (571) 272-2279. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Herng-der Day October 31, 2005

Mayhan Thai Phan Patent Examina Patent Au: 2128